Symtuza®

darunavir/cobicistat/emtricitabine/
tenofovir alafenamide tablets
800mg/150mg/200mg/10mg

Start the conversation by asking the right questions.

Ask your doctor the following questions to see if SYMTUZA® could be right for you.

- Can I start treatment right away?

- How can treatment help prevent HIV from being transmitted?

- How do I know if an HIV treatment is going to be effective?

- Are certain HIV medications more closely associated with treatment-related weight gain than others?

- What should I know about HIV treatment and side effects, like weight gain or fatigue?

- How might different HIV medications impact my long-term health or my existing health conditions?

- Which HIV treatments can help me reduce my risk of drug resistance and maintain an undetectable viral load?

Learn more about SYMTUZA® at Symtuza.com.

WHAT IS SYMTUZA®?

SYMTUZA® is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and in children who weigh at least 88 pounds (40 kg) who:

- have not received anti-HIV-1 medicines in the past, **or**
- when their healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if SYMTUZA® is safe and effective in children weighing less than 88 pounds (40 kg).

SELECT IMPORTANT SAFETY INFORMATION

WHAT IS THE MOST IMPORANT INFORMATION I SHOULD KNOW ABOUT SYMTUZA®?

SYMTUZA® can cause serious side effects including worsening of hepatitis B virus infection. Your healthcare provider will test you for hepatitis B virus (HBV) before starting treatment with SYMTUZA®. If you have HBV infection and take SYMTUZA®, your HBV may get worse (flare-up) if you stop taking SYMTUZA®. Do not stop taking SYMTUZA® without first talking to your healthcare provider. Do not run out of SYMTUZA®. Refill your prescription or talk to your healthcare provider before your SYMTUZA® is all gone.

Please read additional Important Safety Information on the next page and click here for full [Product Information](#), including Boxed WARNING for SYMTUZA®, and discuss any questions you have with your doctor.

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IMPORTANT SAFETY INFORMATION

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SYMTUZA® can cause serious side effects including:

- **Worsening of hepatitis B virus infection.** Your healthcare provider will test you for hepatitis B virus (HBV) before starting treatment with SYMTUZA®. If you have HBV infection and take SYMTUZA®, your HBV may get worse (flare-up) if you stop taking SYMTUZA®.
  - Do not stop taking SYMTUZA® without first talking to your healthcare provider.
  - Do not run out of SYMTUZA®. Refill your prescription or talk to your healthcare provider before your SYMTUZA® is all gone.
  - If you stop taking SYMTUZA®, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection or give you a medicine to treat your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking SYMTUZA®.
- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with SYMTUZA®. Liver problems can also happen during treatment with SYMTUZA® in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with SYMTUZA®.
- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
  - Skin or the white part of your eyes turn yellow
  - Dark "tea-colored" urine
  - Light-colored stools
  - Loss of appetite for several days or longer
  - Nausea
  - Vomiting
  - Stomach area pain

SYMTUZA® may cause severe or life-threatening skin reactions or rashes which may sometimes require treatment in a hospital. Call your healthcare provider right away if you develop a rash. **Stop taking SYMTUZA®** and call your healthcare provider right away if you develop any skin changes with symptoms below:

- Fever
- Tiredness
- Muscle or joint pain
- Blisters or skin lesions
- Mouth sores or ulcers
- Red or inflamed eyes, like "pink eye" (conjunctivitis)

Who should not take SYMTUZA®?

- Do not take SYMTUZA® with any of the following medicines: alfuzosin, carbamazepine, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, ergot-containing medicines (such as: dihydroergotamine, ergotamine tartrate, methylergonovine), ivabradine, lomitapide, lovastatin or a product that contains lovastatin, lurasidone, midazolam (when taken by mouth), naloxegol, phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort, sildenafil when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin, or triazolam.
- Serious problems can happen if you take any of these medicines with SYMTUZA®. This is not a complete list of medicines. Therefore, tell your healthcare provider about all medicines you take.

Before taking SYMTUZA®, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems (including hepatitis B or hepatitis C), have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition.
- are pregnant (if you become pregnant while taking SYMTUZA®), or plan to become pregnant. It is unknown if SYMTUZA® will harm your unborn baby.
  - SYMTUZA® should not be used during pregnancy.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take SYMTUZA®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, topical creams, vitamins, and herbal supplements. Some medicines interact with SYMTUZA®. Keep a list of your medicines to show your healthcare provider and pharmacist. **Do not start taking a new medicine without telling your healthcare provider.**

HOW SHOULD I TAKE SYMTUZA®?

- Take SYMTUZA® 1 time a day with food.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF SYMTUZA®?

SYMTUZA® may cause serious side effects including:

- See **"What is the most important information I should know about SYMTUZA®?"**
- **Immune system changes** can happen in people who start HIV medications.
- **New or worse kidney problems, including kidney failure.**
  - Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking SYMTUZA®.
- **Too much lactic acid in your blood (lactic acidosis).**
  - Too much lactic acid is a serious but rare medical emergency that can lead to death. **Tell your healthcare provider right away if you get these symptoms:** weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including SYMTUZA® can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking SYMTUZA®.
- **Changes in body fat** can happen in people taking HIV-1 medications.
- **Increased bleeding** can occur in people with hemophilia who are taking SYMTUZA®.

The most common side effects of SYMTUZA® are: diarrhea, rash, nausea, fatigue, headache, stomach problems, and gas.

These are not all of the possible side effects of SYMTUZA®.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *http://www.fda.gov/medwatch* **or call 1-800-FDA-1088.** You may also report side effects to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

Please see full Product Information, including Boxed Warning for SYMTUZA®.

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